In the Specification:

Listed below are amended paragraphs of the Specification.

On page 4, please delete the paragraph beginning on line 12, and substitute therefor:

In one embodiment, the catheter ~~of the present invention~~ derives technical advantages as being adapted to be percutaneously positioned into the aorta via a femoral artery with the large lumen in the collapsed position. This large lumen has a very thin wall facilitating inflation/collapsing about the main catheter body, preferably being comprised of polyethylene. Subsequently, by infusing a fluid, such as oxygenated blood, into the large lumen, the large lumen self expands due to fluid pressure of the fluid flowing therethrough to the lumen distal end. In another embodiment, the catheter can be inserted into other access vessels such as a subclavian artery.

On page 4, please delete the paragraph beginning on line 21, and substitute therefor:

The ~~present invention~~catheter derives technical advantages as a single catheter having multiple lumens and a reduced overall diameter. The catheter has a relatively small overall diameter during insertion through access arteries to the aorta with the large lumen in the collapsed position during advancement. This small diameter provides good control of the catheter during insertion, reducing the risk of damaging or traumatizing the lining of the artery. The catheter main body provides advancement of the large lumen within the vessel, and the catheter is sufficiently rigid to avoid kinking during insertion.

On page 5, please delete the paragraph beginning on line 8, and substitute therefor:

The ~~present invention~~catheter has other numerous uses and advantages in the surgical field whereby a large catheter lumen is required for exchanging a fluid to a body vessel, but the

body vessel has a relatively small diameter and is difficult to navigate in and is susceptible to trauma. For instance, the ~~present invention~~catheter is ideally suited for use as a ureter catheter as well.

On page 8, please delete the paragraph beginning on line 2, and substitute therefor:

Figure 1 is a perspective view of the catheter ~~of the present invention~~ shown femorally inserted into the aorta to provide arterial return of oxygenated blood when the catheter is used as an aortic catheter, wherein the large inflatable lumen is in the collapsed position during insertion to minimize trauma to the arteries and then inflated during delivery of oxygenated blood;

Figure 2 is a longitudinal cross section of the catheter ~~of the present invention~~ shown in Figure 1 including the large inflatable/collapsible lumen shown in the collapsed state as carried by the catheter body for advancement into a body vessel, such as for the procedure shown in Figure 1;

Figure 3 is a longitudinal cross section of the catheter of Figure 1 illustrating the large lumen in the expanded state when fluid flows therethrough into the body vessel;

Figure 4 is a transverse cross-section of the catheter taken along line 4-4 in Figure 2 with the large lumen in the collapsed state;

Figure 5 is a transverse cross-section of the catheter taken along line 5-5 in Figure 3 with the large lumen in the expanded state;

Figure 6 is a view of the catheter ~~of the present invention~~ inserted into the aorta via the left subclavian artery;

Figure 7a is an isometric side view of one embodiment of the catheter with a tapered distal end;

Figure 7b is an isometric side view of another embodiment of the catheter with a tapered distal end;

Figure 7c is an isometric side view of another embodiment of the catheter with a tapered distal end;

Figure 7d is an isometric side view of another embodiment of the catheter with a tapered distal end;

Figure 8 is an isometric side view of another embodiment~~ of the present invention~~;

Figure 9a is an isometric drawing of another embodiment ~~of the present invention~~ showing the flexible lumen in a collapsed position inside a cover;

Figure 9b is an isometric drawing of the embodiment illustrated in Figure 9a showing a partially removed cover;

Figure 9c is a detailed isometric drawing of a diffused nozzle used in some embodiments ~~of the present invention~~;

Figure 9d is a detailed isometric drawing of another diffused nozzle used in some embodiments~~ of the present invention~~;

Figure 9e is a transverse cross-sectional drawing of the embodiment shown in Figure 9a;

Figure 10a is a view of one embodiment ~~of the present invention~~ inserted into the aorta via the left subclavian artery;

Figure 10b is a view of the embodiment shown in Figure 7b inserted into the aortic arch and perfusing the descending aorta;

Figure 10c is a view of the embodiment shown in Figure 7b inserted into the aorta arch;

Figure 10d is a view of the embodiment shown in Figure 7d inserted into the aortic arch and perfusing the descending aorta;

Figure 11a is an isometric side view of one embodiment ~~of the invention~~ showing an expanded lumen;

Figure 11b is an isometric side view of one embodiment ~~of the invention~~ showing an expanded lumen in a partially expanded position;

Figure 11c is an isometric side view of one embodiment ~~of the invention~~ showing an expanded lumen folded back into the body of a catheter;

Figure 11d is an isometric side view of one embodiment ~~of the invention~~ showing a lumen rolled into the body of a catheter; and

Figure 11e is an isometric side view of one embodiment ~~of the invention~~ showing an expanded lumen having a large diameter.

On page 11, please delete the paragraph beginning on line 2, and substitute therefor:

Referring now to Figure 1, there is shown generally at 10 a catheter according to the preferred embodiment ~~of the present invention~~ used as an aortic balloon catheter femorally inserted into a patient and advanced into an ascending aorta 11 of a heart 12. Catheter 10 is seen to have a balloon member 14 positioned and expanded within the ascending aorta 11 to occlude the aorta above an aortic valve 16. Catheter 10 is further seen to include a cardioplegia delivery/venting port 18 and a pressure sensing port 20. Both ports 18 and 20 are defined distal of the balloon member 14 for use within the ascending aorta above the aortic valve 16. Catheter 10 is further seen to include a large integral expandable/collapsible lumen 22 defined between a main catheter body 24 and a thin-walled sleeve member 40 disposed about and carried by the main catheter body 24. Lumen 22 terminates proximate the distal end of the catheter 10, but proximal the balloon member 14. Lumen 22 is ideal for providing arterial return of oxygenated blood to the ascending aorta from an extracorporeal pump (not shown).

On page 11, please delete the paragraph beginning on line 17, and substitute therefor:

The ~~present invention~~catheter derives technical advantages as a catheter having a large lumen 22 that can be collapsed when inserted through a smaller access artery, such as the femoral artery, and into the ~~ascendina~~ ascending aorta. The catheter has a reduced overall diameter during insertion, thereby reducing trauma to the artery and improving control during insertion. The fluid pressure of the oxygenated blood delivered through lumen 22 causes sleeve member 40 to self expand from a collapsed state within the artery, whereby the diameter of the large lumen 22 is sufficient to provide oxygenated blood at a sufficient rate and pressure to perfuse the human body. As shown, a single catheter 10 is suitable for providing multiple functions during aortic perfusion, without requiring a second catheter and minimizing damage to the lining of the aorta.

On page 12, please delete the paragraph beginning on line 7, and substitute therefor:

Referring now to Figure 2 and Figure 3, there is shown a longitudinal cross section of catheter 10 according to the preferred embodiment~~ of the present invention~~. Sleeve member 40 is illustrated in the collapsed state in Figure 2, and in the expanded state in Figure 3. A transverse cross-section of catheter 10 having the sleeve member 40 in the collapsed state taken along line 4-4 in Figure 2 is shown in Figure 4. A transverse cross-section of catheter 10 having the sleeve member 40 in the expanded state taken along line 5-5 in Figure 3 is shown in Figure 5. It is noted again that the catheter 10 ~~of the present invention~~ is ideally suited as an aortic balloon catheter, however, the catheter 10 has other intended uses as well, such as a ureter catheter, and limitation for use as an aortic balloon catheter as described with reference to Figure 1 is not to be inferred.

On page 14, please delete the paragraph beginning on line 19, and substitute therefor:

In the preferred embodiment~~ of the present invention~~, the inner diameter of lumen 22 in the expanded position, as shown in Figure 3 and Figure 5, is substantially larger than the outer diameter of the main catheter body 24, such as a 4 to ~~I~~<u>1</u> ratio. For example, the inner diameter of expanded lumen 22 may be about 10.7mm (32 fr.), and the outer diameter of main catheter body 24 may be about 2.7mm (8 fr.), although limitation to these dimensions is not to be ~~iliferred~~<u>inferred</u>. This expandable lumen 22 is ideal for delivering a fluid, such as oxygenated blood, at a large fluid rate, whereby the smaller lumens 26, 28 and 30 are rather small and suited for their intended use, such as previously discussed. The main catheter body 24 is comprised of a suitable material such that it will not kink or buckle during insertion into the intended body vessel, such as the aorta or urethra. If desired, one of the lumens, such as lumen 26, can be provided with a malleable guide wire to selectively provide rigidity to the catheter body 24 and aid insertion of catheter 10 into the intended body vessel.

On page 15, please delete the paragraph beginning on line 12, and substitute therefor:

Cessation of fluid flow from the pump (not shown) through the lumen 22 will cause the lumen member 40 to collapse about the catheter body 24. Removal of catheter 10 from the body vessel, generally after fluid flow through lumen 22 has ceased, will further constrict lumen member 40 to cause any remaining fluid in lumen 22 to be dispensed out the distal opening 46 of the lumen 22. The lumen member 40 having a very flexible and thin wall will collapse about catheter body 24 as forces from the body vessel compress the lumen member 40 into its collapsed position, thus facilitating the easy removal of catheter 10 from the body vessel. The reduced catheter diameter during withdrawal further reduces trauma to the body vessel, which is a further technical advantage~~ of the present invention~~.

On page 16, please delete the paragraph beginning on line 2, and substitute therefor:

Still referring to Figure 2 and Figure 3, the proximal end of catheter 10 is seen to have versatile features that have additional technical advantages. Each patient has different physical attributes and dimensions, and thus, the catheter ~~of the present invention~~ can be adapted to have a sufficient length for use within each particular patient. The proximal end of catheter 10 is seen to have a substantially rigid tubular body member generally shown at 50. The proximal end of the thin wall lumen member 40 is seen to be disposed about and sealingly attached about the circumference of the body member 50 distal end shown at 52. Notably, the proximal end of the lumen member 40 is seen to be bunched together in an accordion or serpentine like arrangement. This allows the length of the lumen member 40 defined distal of the distal end 52 to be selectively adjusted along with the length of catheter body 24 slidably extending through body member 50, thereby allowing the physician to selectively adjust the length of the catheter from body member distal end 52 to the catheter distal end 54. As indicated by the arrows, the main

catheter body 24 is seen to be longitudinally slidably adjustable within a flow passageway 56 extending within body 50. Main catheter body 24 can be selectively adjusted by the physician such that it can be extended or retracted through body member 50 and proximal end 58. To provide a sealed, fluid tight, lumen 56, the proximal end 58 of body member 50 has positioned therein a hemostasis valve 60 sealingly- disposed about the main catheter body 24. Valve 60 is sealingly engaged against the inner wall of passageway 56 to prevent oxygenated blood 66 from back flowing through proximal end 58, and to provide friction holding catheter body 24 in place at the selected position. The main catheter body 24 is longitudinally and slidably adjustable through valve 60 by the physician.

On page 17, please delete the paragraph beginning on line 6, and substitute therefor:

A flanged connector 62 is seen to form a Y connection in combination with proximal end 58 and has a passageway 64 extending therethrough in fluid communication with passageway 56. An oxygenated blood source 66 is fluidly coupled to member 62 and provides oxygenated blood to the catheter 10 via the passageway 64, lumen ~~'06~~<u>56</u>, and ultimately to the expandable/collapsible passageway 22 for delivery to the artery via the opening 46 and openings 42. The proximal end of catheter 10 is seen to have extending therefrom three separate passageways, namely, a passageway 70 in fluid communication with lumen 30 and coupled to an inflation source 72, a passageway 74 in fluid communication with lumen 28 and coupled to a pressure sensor device 76, and a passageway 78 in fluid communication with lumen 26 and coupled to a fluid delivery source 80. Each passageway connects to a respective connector, as shown in Figure 1.

On page 17, please delete the paragraph beginning on line 19, and substitute therefor:

The outer diameter of main catheter body 24 is significantly smaller than the outer diameter of passageway 56 extending through body member 50. This creates a sufficient passageway 56 about main catheter body 24 for oxygenated blood to be communicated therethrough ~~as~~ at a sufficient rate and pressure to perfuse the human body as shown in Figure 1. It is noted that the outer diameter of passageway 56 is less than the diameter of passageway 22 formed by the fully inflated lumen member 40, and thus, the fluid pressure will be higher through passageway 56 than the fluid pressure within passageway 22 during use. However, the short catheter portion that the blood is at a higher pressure is relatively short in relation to the overall length of the catheter 10. Thus, the required pressure for the oxygenated blood source 66 is suitable for delivery of oxygenated blood to an artery of the body, such as the aorta illustrated in Figure 1. As shown in Figure 3, the diameter of the lumen member 40 between proximate body member 50 and a transition 82 is reduced with respect to the lumen member 40 distal of transition 82 as this portion and the body member distal end 52 typically are positioned in the smaller access artery. The body member 50 has sufficient strength to facilitate insertion into a smaller access artery.

On page 18, please delete the paragraph beginning on line 16, and substitute therefor:

Referring now to Figure 6, there is shown an alternative ~~preferred~~ method of the use ~~of the present invention~~ whereby the catheter 10 is inserted into the ascending aorta via the left subclavian artery shown at 90. Like the femoral artery, the left subclavian artery can also be used as an access vessel for positioning the catheter 10 within the ascending aorta, as shown. The left subclavian artery, like the femoral artery, has a diameter less than the larger aortic artery and thus limits the overall diameter of the catheter that can be inserted therethrough. The ~~present invention~~catheter is ideal for insertion through small arteries for ultimate positioning within a larger artery, such as for the purpose of delivering fluids into the large artery at suitable flow rates while minimizing trauma to the arteries by the catheter.

On page 19, please delete the paragraph beginning on line 6, and substitute therefor:

It is intended that other arteries are suitable as access sites for the ~~present invention~~catheter as well, such as the left carotid artery 92 and the right carotid artery 94 as shown in Figure [[4]]6. The desired insertion artery is left to the choice of the surgeon and will depend upon many criteria and will vary from patient to patient.

On page 19, please delete the paragraph beginning on line 11, and substitute therefor:

Figures 7-11 describe various examples and other embodiments~~ of the present invention~~. For brevity and clarity, a description of those parts which are identical or similar to those described in connection with embodiments illustrated in Figures 1 through 6 will not be repeated. Reference should be made to the foregoing paragraphs with the following description to arrive at a complete understanding of these embodiments. It is understood that features of various examples and embodiments may be interchanged, combined or otherwise reconfigured.

On page 19, please delete the paragraph beginning on line 19, and substitute therefor:

Referring to Figure 11a, which is an isometric side view of another embodiment ~~of the present invention~~ designated generally as a catheter 1100 which includes an elongated collapsible lumen 1102, a catheter body 1108, and a connection 1110.

On page 21, please delete the paragraph beginning on line 12, and substitute therefor:

In another embodiment, the collapsible lumen could have a smaller cross-sectional diameter or a reduced cross-sectional diameter at the distal end of the member. Referring to

Figure 7a, which illustrates an isometric view of another embodiment ~~of the present invention~~ designated generally as catheter 700 which includes an elongated collapsible lumen 702, a catheter body 708, and a connection 710. The distal end of collapsible lumen 702 terminates at nozzle 718. The diameter of nozzle 718 tapers to a reduced diameter opening 720 or, alternatively, no opening. In either case, there are a plurality of circumferentially extending side openings 716 disposed longitudinally along nozzle 718. The plurality of side openings create a diffused velocity flow versus the high velocity flow or "jet" flow of a single opening in a standard cannula. The diffused velocity flow reduces the possibility of dislodging micro-emboli from the aorta wall and other trauma to the inside of the aorta.

On page 22, please delete the paragraph beginning on line 21, and substitute therefor:

The collapsible lumen member ~~of the present invention~~ can be attached to a variety of cannulae and catheter bodies. Turning back to Figure 7a, the proximal end of collapsible lumen 702 is joined to a catheter body 708 at point 714. The collapsible lumen 702 is preferably disposed about and sealingly attached about the circumference of the catheter body 708.

On page 24, please delete the paragraph beginning on line 5, and substitute therefor:

The main body section 707 is used to clamp the cannula. The larger diameter of the main body section 707 reduces the pressure drop across the cannula. At the proximal end of the main body section 707 is a connection 710. The connection 710 is attached to the arterial line of a an extracorporeal bypass machine[[,]].

On page 25, please delete the paragraph beginning on line 1, and substitute therefor:

Referring to Figure 7d, which illustrates another embodiment~~ of the present invention~~. In this embodiment, catheter 750 is similar to the catheter illustrated in Figure 7c, except that it is coupled to a balloon member 752. In Figure 7d, the balloon member 752 is in an expanded condition. The balloon member 752 is used to occlude an artery, and is positioned longitudinally between a body portion 753 and a collapsible lumen 722. Catheter 750 is used to perfuse, and the balloon member 752 occludes the aorta above an aortic valve 16, as illustrated in Figure 10d. Balloon member 752 is inflated by a separate tube (not shown) running down the interior wall of the catheter body 753.

On page 26, please delete the paragraph beginning on line 6, and substitute therefor:

Referring now to Figure 10a, there is shown an alternative ~~preferred~~ method ~~of the use of the present invention~~ whereby the catheter 700 is inserted into the ascending aorta via the left subclavian artery shown at 90. Like the femoral artery, the left subclavian artery can also be used as an access vessel for positioning the catheter 700 within the ascending aorta, as shown. The left subclavian artery, like the femoral artery, has a diameter less than the larger aortic artery and thus limits the overall diameter of the catheter that can be inserted therethrough. The ~~present invention~~<u>catheter</u> is ideal for insertion through small arteries for ultimate positioning within a larger artery, such as for the purpose of delivering fluids into the large artery at suitable flow rates while minimizing trauma to the arteries by the catheter.

On page 26, please delete the paragraph beginning on line 17, and substitute therefor:

Referring to Figure 10b, there is shown an alternative ~~preferred~~ method ~~of the use of the present invention~~ whereby the catheter 700 is inserted into the aortic arch for perfusing the descending aorta. Like the femoral artery, the aortic arch can also be used as an access vessel for positioning the catheter 700 within the descending aorta, as shown.

On page 27, please delete the paragraph beginning on line 4, and substitute therefor:

Referring to Figure 10d, there is shown an alternative ~~preferred~~ method ~~of the use of the present invention~~ whereby the catheter 750 is inserted into the aortic arch for perfusing the descending aorta. Like the femoral artery, the aortic arch can also be used as an access vessel for positioning the catheter 750 within the descending aorta, as shown. The balloon member 752 is expanded which occludes the aorta above the aortic valve 16 (not shown in Figure 10d).

On page 27, please delete the paragraph beginning on line 16, and substitute therefor:

In another embodiment, illustrated in Figure 9a, a catheter 900 comprises a cover 904 and ~~an~~a tube member 906 to assist in the positioning of the catheter 900. The catheter 900 is similar to the catheter 700, except that a collapsible lumen 902 (not shown in Figure 9a) is folded or collapsed inside the cover 904.

On page 28, please delete the paragraph beginning on line 8, and substitute therefor:

The tube member 906 may be manufactured by any wide variety of stainless steel or other medical grade materials. If a guide wire is used, the tube member 906 may be hollow which allows it to ~~slid~~slide over a guide wire. The interior diameter of tube member 906 is sufficient to allow the tube member 906 to slide over the guide wire. If a guide wire is not used, tube member 906 may be either solid or hollow. At the distal end, the tube member 906 is coupled to a rounded end member 910 as illustrated in Figure 9c. Figure 9c is a detail view of the distal end of the collapsible lumen 902, having circular openings 928. Figure 9d is an alternative embodiment wherein the openings 930 are longitudinal slits. The use of end member 910 reduces the chances of a creating a "whipping" action within the vessel as the tube is snaked

through the vessel. The end member 910 also reduces the chances of scraping the interior of the artery. Furthermore, it ~~is easily~~is easily identifiable in TEE screens. The end member 910 may be made from stainless steel, nylon or any number of medical grade materials. The end member 910 is sealantly attached to the collapsible lumen 902. The tube member 906 runs from the distal end of collapsible lumen 902, through the body of catheter 900, ~~through side~~through side port 908 (Figure 9a).

On page 29, please delete the paragraph beginning on line 10, and substitute therefor:

The surgeon may also choose to position catheter 900 without the aid of a guide wire. Compared to the collapsible lumen 902, the cover 904 is relatively rigid and allows for the insertion and accurate positioning of the collapsible lumen 902 within the artery. Because collapsible lumen 902 is in a collapsed position inside of cover 904, the collapsible lumen 902 has an extremely low profile which significantly reduces the chances of trauma or dislodging ~~plague~~plaque. Once the collapsible lumen 902 is in position, cover 904 may be removed by pulling the sheath longitudinally toward the catheter body 900, as illustrated in Figure 9b. Cover 904 may then be discarded and the collapsible lumen 902 is inflated by fluid pressure created by a roller pump (not shown) once connecting member 912 is connected to an extracorporeal circuit (not shown).

On page 29, please delete the paragraph beginning on line 21, and substitute therefor:

Cessation of fluid flow from the pump in the extracorporel circuit through the collapsible lumen will cause the collapsible lumen to collapse. Removal of the catheter from the body vessel can take place generally after fluid flow through the collapsible ~~lumen has~~lumen has ceased. The removal will further constrict the collapsible lumen and cause any remaining fluid in the collapsible lumen to be dispensed out the openings at the distal end, thus facilitating ~~the~~ easy

removal ~~of the present invention~~ from the body vessel. The reduced catheter diameter during withdrawal further reduces trauma to the body vessel, which is a further technical advantage ~~of the present invention~~.

On page 30, please delete the paragraph beginning on line 9, and substitute therefor:

The ~~present invention~~catheter is also ideal for insertion through small arteries for ultimate positioning within a larger artery, such as for the purpose of delivering fluids into the large artery at suitable flow rates while minimizing trauma to the arteries by the catheter. It is intended that other arteries are suitable as access sites ~~for the present invention~~ as well, such as the left carotid artery 92 and the right carotid artery 94. The desired insertion artery is left to the choice of the surgeon and will depend upon many criteria and will vary from patient to patient.

Please delete the Abstract, and substitute therefor:

A catheter and method of use ~~as~~ may include an aortic balloon catheter having an integral expandable/collapsible lumen. The catheter comprises a main catheter body having a either a single or a plurality of lumens extending therethrough, and further includes an expandable/collapsible lumen disposed thereabout and carried by the main catheter body. The expandable/collapsible lumen has a ~~*relatively large*~~ relatively large diameter when inflated with respect to the main ~~*catheter body*~~catheter body, and is self-inflating by fluid pressure when the fluid flows therethrough. The large inflatable/collapsible lumen is attached at its distal end to the main catheter body and thus is carried therewith into a body vessel, and thus is also supported by the catheter body to avoid kinking. The present invention also achieves technical advantages as a catheter for insertion into any body vessel having a limited diameter and which is susceptible to trauma, such as a urethra.